K062863

OCT 31 2006

510(k) Summary

Device Proprietary Name:	OsteoMed Extended 2.0/2.4 Cannulated Screw System
Device Common Name:	Bone Screw
Classification Name:	HWC, Screw, Fixation, Bone
Name of Submitter:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4600 Fax: (972) 677-4601
Contact Person:	Dawn D. Tindall
Date Prepared:	September 22, 2006

Summary:

This submission describes the OsteoMed Extended 2.0/2.4 Cannulated Screw System indicated for bone fixation of hand and foot following trauma or osteotomy. Screws and washers are intended for single use only.

The OsteoMed Extended 2.0/2.4 Cannulated Screw System is comprised of screws in diameters of 2.0mm (length 6mm to 42mm) to 2.4mm (length 6mm to 52mm). The screws are made from titanium alloy (ASTM F-136). Depth gauges, screwdrivers, drills, countersinks, k-wires, and preparation instruments will also be a part of the system.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Osteomed Cannulated Screw Systems (K010783 and K954330), the BioPro Digital Compression Screw (K963433) and the Millennium Medical Technologies Percutaneous Compression Wire (K031050).

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed Extended 2.0/2.4 Cannulated Screw System does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OsteoMed L.P.
% Ms. Dawn D. Tindall
Regulatory Affairs
3885 Arapaho Road
Addison, Texas 75001

OCT 3 1 2006

Re: K062863
Trade/Device Name: OsteoMed Extended 2.0/2.4 Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: Class II
Product Code: HWC
Dated: September 22, 2006
Received: September 28, 2006

Dear Ms. Tindall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062863

Device Name: OsteoMed Extended 2.0/2.4 Cannulated Screw System

Indications for Use:

The Osteomed Extended 2.0/2.4 Cannulated Screw System is indicated for bone fixation of hand and foot following trauma or osteotomy. Screws and washers are intended for single use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K062863